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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, *et al., ex rel.* Doris Modglin and Russ Milko, Relators, vs. DJO GLOBAL INC., DJO LLC, DJO	Case No. CV12-7152-MMM (JCGx) **RELATORS' OPPOSITION TO DEFENDANTS' MOTION TO STAY DISCOVERY**

FINANCE LLC, BIOMET, INC., EBI, LP, and EBI, LLC, Defendants.	Hearing Date: On the briefs, per Feb. 5, 2014 Order (Dkt. 53)

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INTRODUCTION

It is beyond question that a district court has the authority to order a stay of discovery, but where the pending Motion to Dismiss which supposedly justifies such a stay not only mischaracterizes the theory of liability, but fails to address pertinent authorities cited in the complaint itself, both the pending motion and the motion for stay ultimately rest upon grounds that are flimsy at best. Just as the district court has broad discretion to order a stay of discovery under appropriate circumstances, where it appears that a stay would ultimately serve only to cause unnecessary delay in the progress of the case, the Court has equally broad discretion to deny the request.

Here, the Defendants' requested stay falls into the latter category. Neither their pending Motion to Dismiss nor the instant motion offer sound grounds for the requested stay. Indeed, to give credence to Defendants' mistaken view of the law would require the Court to disregard Ninth Circuit authority, ignore applicable regulatory provisions, and to disregard the position stated by the Secretary of the Department of Health and Human Services regarding the experimental nature of devices which have not received a "safe and effective" determination from the FDA. Defendants' contentions also involve improperly placing individual physicians in the role of final arbiters of what is "reasonable

and necessary" for coverage, a view which runs directly counter to the position the Government has explicitly taken in various cases around the country.

When Defendants' erroneous approach is unraveled, it is apparent that the Defendants own refusal to address applicable law in light of the theory of liability actually alleged in the SAC lies at the heart of all of Defendants' challenges to the sufficiency of that pleading. Although this is neither the time or place to fully delineate each and every point which will be addressed in opposition to the pending motion to dismiss,[1] because questions such as materiality and sufficient particularity require, at a minimum, a correct view of the law and the case, the overarching defects addressed herein serve to illustrate that Defendants' confidence in the merits of their motion to dismiss is fundamentally misplaced.

Finally, Defendants are incorrect in their assertion that it is the Relators who have caused unnecessary delay in this case. Relators stand ready to proceed with this action, and are willing to explore with opposing counsel potential solutions which might ameliorate the burdens of discovery, while it is the Defendants who have declined to consider any compromise which might otherwise have obviated the necessity of their motion. Given all these

[1] Thus, discussion of other serious defects, such as Defendants failure to cite pertinent Ninth Circuit authority regarding the correct application of Rule 9(b) in a false claims case, or Defendants' subtle distortion of the FCA scienter standard, are matters which cannot be covered here.

circumstances, the absolute stay of discovery which Defendants seek should be denied.

I. THE DEFENDANTS' MOTION TO DISMISS PRESENTS A WARPED VIEW OF APPLICABLE LAW WHICH IS WHOLLY INADEQUATE TO JUSTIFY THE SUBSTANTIAL DELAY THE STAY WOULD INVOLVE.

That the Relators and Defendants in this case differ in their views concerning applicable law is hardly surprising. What is surprising, however, is the extraordinary propositions Defendants evidently expect the Court to adopt based upon a motion to dismiss which has, for the most part, simply ignored the legal authorities cited within the SAC itself.

A central contention in Defendants' Motion to Dismiss is that the Relators' theory of liability supposedly "conflates" the roles and responsibilities of FDA and CMS. According to Defendants:

> FDA is responsible for approving a device through the PMA process. 21 U.S.C. § 360(a)(1)(C); 21 C.F.R. Part 814. And, to be sure, a device's PMA approval is based on FDA's evaluation of its safety and effectiveness. *But once that process is complete*, the FDA does not regulate *physicians' ability* to prescribe the approved device to treat their patients for any use.

(Doc. 46, 9:14-19; emphasis added.) After a paragraph which again states that the FDA does not prohibit individual physicians from prescribing a device for an off-label use, Defendants go on to state that:

> CMS, in contrast, is responsible for setting coverage limitations on when *FDA-approved medical devices* will be covered by Medicare -- i.e, what uses CMS considers to be 'reasonable and necessary.' 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.15(k)(1).

(Doc. 46, 10:10-13; emphasis added.) Defendants conclude this line of reasoning by stating that:

> The NCD issued by CMS and the LCDs issued by Medicare carriers embody the government's discretionary determination of what uses Medicare covers for what devices. Because neither the NCD nor the LCDs make coverage contingent on *FDA-approved uses* or *particular regions of the spine*, neither the CMS-1500 nor the Certificate of Medical Necessity requires a DME-provider to specify what region of a patient's spine will be treated or whether the device's PMA-approval relates to that region.

(Doc. 46, 10:10-13; emphasis added.)

Restated more straightforwardly, Defendants contend that: (1) once a device has received Pre-Market Approval, it can thereafter be put to *any* use (so

long as a physician has prescribed it), regardless of whether that particular use is among those for which the FDA originally found the device to be "safe and effective"; and (2) that, so long as the NCD/LCDs which govern osteogenic stimulators neither expressly required FDA-approval nor specifically prohibited that particular off-label use, Defendants were under no legal obligation to inform any of the federally-funded programs which they bill for the cervical use that taxpayers' money is going to pay for a particular use for which the device has *never* been found to be "safe and effective" by the FDA.

Given the extraordinary nature of this position, it might be expected that Defendants' Motion to Dismiss would have at least included a thorough discussion of the authorities cited in the complaint, including, for example, the following Ninth Circuit Court authority:

> FDA review and Medicare coverage review have different purposes. *Id.* FDA review seeks to determine whether a device is 'safe and effective' such that it can be marketed to the general public. By contrast, Medicare coverage review seeks to determine whether the device is 'reasonable and necessary' for treatment such that the device is worth the government's money. Medicare Benefit Policy Manual, ch. 15, § 110.1[C][2]. **To be 'reasonable and necessary' for treatment, a device must be 'safe and effective,'** but other

> considerations are also relevant -- like whether there are less costly but equally effective devices available. *Id.* As the Fourth Circuit held in Almy, '[w]hile FDA approval may . . . inform the Secretary's decision as to whether a device is 'reasonable and necessary,' it cannot tie the Secretary's hands.' 679 F.3d at 308.

International Rehabilitative Sciences Inc. v. Sebelius, 688 F.3d 994,1002 (9th Cir. 2012) ; emphasis added, quoting *Almy v. Sebelius*, 679 F.3d 297, 308 (4th Cir. 2012). In other words, the proper relationship between the FDA's finding of "safe and effective" and a CMS finding of "reasonable and necessary" is that although the CMS can still *deny* coverage, even when a particular device has already been found to be "safe and effective" by the FDA, a device *must* **first** be deemed "safe and effective" simply in order to qualify for consideration under the "reasonable and necessary" coverage standard.

More specifically, the decision of whether coverage should be allowed must take into account, " -- Whether the item has been approved for marketing by the Food and Drug Administration (FDA) and is otherwise generally considered safe and effective ***for the purpose intended*** ..." Centers for Medicare & Medicaid Servs., Publ'n No. 100-03, *National Coverage Determinations ("NCD") Manual, § 280.1 Durable Medical Equipment Reference List*; emphasis added. This is language which simply cannot be reconciled with the idea that, so

long as a device has received pre-market approval for one intended use, all other *unapproved* uses must then also be covered.

As the Ninth Circuit also noted in *Int'l Rehabilitative Sciences*, "the *type* of FDA clearance is relevant to whether Medicare will cover a device" (688 F.3d at 1002; emphasis in original), a point also reflected in 42 C.F.R. § 405.201 (a)(1), "CMS uses the FDA categorization of a device as a factor in making Medicare coverage decisions." It is therefore significant that the devices involved here are categorized as Class III devices, because this class of device is the most "intensely" regulated of all:

> The FDA's regulation centers on the degree of regulatory control necessary to ensure the safety and efficacy of a particular medical device. Class III significant risk devices are the most intensely regulated devices because the devices *present a potential, serious risk of illness or injury*. See 21 U.S.C. §§ 351, 360c, 360e, 360j; ; 21 C.F.R. § 812.3(m) ('A "significant risk device" is one that presents a potential for serious risk to the health, safety, or welfare of a subject.'). The regulations are of substantial importance in preventing impairment of human health. Typically, since minimal safety information as to these devices exists prior to FDA approval, Class III devices gain approval *only after successful completion of the FDA's*

> *most stringent review process -- a lengthy undertaking that includes a careful examination of valid scientific test data*. Only in this way can the FDA satisfy its duty to the public *to ensure the safety and effectiveness of significant risk devices*. Class III devices typically require premarket approval (PMA) or an investigational device exemption (IDE).

United States v. Huggins, 2011 U.S. Dist. LEXIS 142869, *3-*4 (E.D. Pa. Dec. 13, 2011); emphasis added.

Because of this stringent regulatory control over Class III devices, the PMA process is not just a one-time event, after which the tested device is "home free." Rather, if at any time after pre-market approval has been initially obtained the manufacturer wishes to make a change which could affect the safety or effectiveness of the device, the manufacturer must seek and obtain a PMA supplement, which is a separate assessment of the "safety and effectiveness" of the device for the new use. Thus, as the FDA explains:

> Changes for which an applicant ***must submit*** a PMA supplement include, but are not limited to, the following types of changes if they affect the safety or effectiveness of the device:
>
> - *new indication for use of the device*;

PMA Supplements and Amendments (1/6/14); emphasis added.[2] Furthermore, because a manufacturer's failure to adhere to these strict requirements can result in criminal sanctions, the proposition Defendants are pressing the Court to adopt in this case would amount to a rule which could perversely *require* federally funded programs to pay for particular uses, even where they constituted criminal misbranding and adulteration.[3]

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[2] This FDA article addressing PMA supplements can be located at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm050467.htm#when

[3] Thus, in the *Huggins* case:

> Huggins pled guilty as a responsible corporate officer to the introduction into interstate commerce of adulterated and misbranded medical devices - in this case, two Class III significant risk medical devices, SRS mixed with barium sulphate and XR - in violation of 21 U.S.C. §§ 331(a) and 333(a)(1). Plea Agreement, ¶¶ 1, 9(a)-(j). These devices *were adulterated because they were required to have, but did not have in effect an approved application for premarket approval or an approved investigational device exemption*. *Id.* § 351(f)(1)(B). In part, the devices were misbranded because their labeling did not bear 'adequate directions for use,' *id.* § 352(f), and because the FDA was not provided with timely premarket notification of a ***new intended use prior to the introduction of the devices into interstate commerce for such use***, *id.* § 352(o). The maximum statutory penalty for any person who violates a provision of *§ 331* is imprisonment for not more than one year. *Id.* § 333(a).

Huggins, 2011 U.S. Dist. LEXIS 142869, at *5-*6.

It would be one thing if, in their motion to dismiss, the Defendants had examined or distinguished, or indeed engaged in any kind of meaningful discussion of the authorities noted above, all of which were specifically cited in the SAC.[4] Defendants, however, have failed to even mention these authorities anywhere in their pending Motion to Dismiss.

Indeed, the closest Defendants have come to acknowledging any of these authorities is when Defendants contend that, "Similarly off-base is the SAC's reference to 'experimental" devices as excluded from Medicare coverage. SAC ¶ 23," a statement which is followed by a citation to 42 C.F.R. 405.201(b). (Doc. 46, 12:5-8.) Defendants thus make only a brief, passing reference to the provision which states that CMS *may* consider coverage of certain devices which have been accorded an investigational device exemption (a circumstance not applicable here), but nevertheless completely fail to address the provision which immediately precedes it, which establishes that the CMS does indeed use "the FDA categorization of a device as a factor in making Medicare coverage decisions." 42 C.F.R. 405.201(a).

Furthermore, the reference in Paragraph 23 of the SAC of which defendants are so critical includes the statement made in the Reply Brief for

[4] See SAC (doc. 37-2), 6:28, ¶ 10, n. 6; 7:27-28, n. 7; 12:18-19, ¶ 22, n. 11; and 12:24-25, ¶ 23, n. 12.

Appellant Kathleen Sebelius in the *Int'l. Rehabilitative Sciences* case, " . . . [A] device that has not been shown to be effective remains experimental . . . -- this is nothing other than common sense." (Doc. 37-2, SAC ¶ 23, 15-16.) Thus, what the Defendants deride as "off-base" is the position formally asserted before the Ninth Circuit Court by the Secretary of the Department of Health and Human Services, who has authority over both the CMS and the FDA, and who is the ultimate authority on questions of coverage.

The points covered here certainly do not cover every defect in Defendants' Motion to Dismiss, but do provide some indication of why Defendants' heavy reliance upon the supposed merits of that pending motion in their current motion is unwarranted. Defendants are equally misguided in their attempt to seek cover under the physician's authority to prescribe "off-label" uses, and in their mistaken understanding of the theory of liability presented in the SAC.

II. DEFENDANTS' MOTION TO DISMISS MISAPPREHENDS BOTH THE ROLE OF THE PHYSICIAN AND THE THEORY OF LIABILITY.

A. Physicians Are Not the Final Arbiters of Coverage.

Defendants state that Relators' theory is "that Medicare coverage rules prohibit reimbursement for Defendants' FDA-approved devices for any use other than the specific use that FDA approved through the pre-market approval process." Defendants contend that this proposition is "unsupported," and one

which the courts have supposedly "repeatedly rejected," because: (1) "*relevant* Medicare provisions contain no such condition" and (2) "the Supreme Court, the Ninth Circuit, and this Court have all recognized that *physicians* can use their medical judgment to prescribe FDA-approved devices for both 'on-label' and 'off-label' uses." (Doc. 51, 2:23- 3:2; emphasis added.) Some of the problems with what Defendants' consider to be "relevant" law have been addressed above. Defendants' mistaken view of the role the physician plays in the claims process is, however, equally flawed.

Contrary to defendants' assertion, Relators do not dispute a physician's authority to prescribe a drug or device for an "off-label" use. This case, however, is not about who can *prescribe* an off-label treatment, but who *pays for it*.

Medicare operates "much like private medical insurance." *Int'l Rehabilitative Sciences*, 688 F.3d at 997. In the private setting, just because a patient's doctor believes that the use of a particular drug or device may be appropriate for that patient does not necessarily mean that the patient's insurance plan will necessarily cover the cost, and the same is true for the federally funded programs involved here. As explained in *Svidler v. Department of Health and Human Services, et al.*, 2004 U.S. Dist. LEXIS 18325 (N.D. Cal. Sept. 8, 2004):

> When a device is approved for one purpose and used outside of its approval (either for a different purpose or in a different dosage), that use is

> deemed 'off label.' Plaintiff correctly notes that the FDA can restrict a company from marketing for off label uses, but cannot prevent a doctor from prescribing a device for an off label use for any purpose she deems medically necessary. *Washington Legal Foundation v. Friedman,* 13 F. Supp.2d 51 (D.D.C. 1998). Plaintiff then argues that because she is allowed to prescribe off label uses, Medicare must pay for off label uses. This leap of logic *is unwarranted.* Medicare excludes payments for all treatment not necessary, *but does not require payment for all necessary treatments*. *Goodman v. Sullivan,* 891 F.2d 449, 451 (2nd Cir. 1989).

Svidler, 2004 U.S. Dist. LEXIS 18325, *13-*14; emphasis added.[5]

It is therefore the Defendants, not Relators, who have evidently seriously misunderstood the role which the physician plays in this context. Doctors are simply not the final arbiters of what will, or will not, be covered by a federally funded healthcare program. In fact, if Defendants mistaken view was correct, there would be no *need* for local or national coverage determinations, for the regulations which so stringently govern Class III devices, or for the regulations and coverage guidance materials which delineate the relevance of a "safe and

[5] *Svidler* was cited in the SAC (doc. 37-2) at 12:24-25, ¶ 23, n. 12. Because this authority clearly acknowledges that an individual physician can prescribe for "off-label" uses, the Defendants' assertion that Plaintiffs have supposedly failed to grasp this point (doc. 51, 2:23- 3:2) is itself an unsupported contention.

effective" determination by the FDA to ultimate coverage of a device as "reasonable and necessary." Instead, federally funded programs like Medicare would operate in a manner like no other health care insurance carrier, unable to curb experimentation on their beneficiaries and unable to control the costs of treatments which have not been deemed "safe and effective" by the FDA. Under such circumstances, providers would be entitled to payment for whatever procedure or use of a device they were able to dream up, without regard for safety and efficacy, so long as a single physician was willing to prescribe such a use. In short, if Defendants' view was correct, and individual physicians had the final word on payment, there would simply be no need for the entire claim reimbursement process to exist.

B. Defendants Misstate the Theory of Liability Pled in the SAC.

Defendants also ignore the factual allegations of the complaint in assuming that Relators are attempting to allege a "promotion" theory in their SAC. FCA cases involving "promotion" usually involve a scenario in which the manufacturer of the drug or device has, through various means, induced a physician to prescribe an "off-label" use and then bill a federally funded program for such use, in other words, where the defendant has knowingly and foreseeably caused *the physician* to present "a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729 (a)(1)(A).

Here, however, it is the Defendants' *own* presentation of false claims which is at issue, not some "promotion" scheme in which a manufacturer is accused of indirectly "causing" the presentation of such claims. It is the Defendants, not the doctors, who present the bill for payment (doc. 37-2, SAC ¶ 26, 14:4-12). Furthermore, although these Defendants necessarily know that their own manufactured devices have not received FDA approval for cervical use, the same certainly cannot be said of the physicians, who may not even be aware that they are prescribing for an "off-label" use when they do so.[6]

Thus, for Defendants to attempt to shield themselves by directing attention to the *physician's* ability to prescribe the device for an off-label use (doc. 46, 9:18-23) is doubly erroneous. The success of the fraudulent scheme alleged in the SAC does not depend upon actively persuading a physician to prescribe a use which the physician *knows* to be an "off-label" use.[7] Even if, however, the physician was fully aware that prescribing the device for cervical use constituted

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[6] Unless the physician is first made aware of which manufacturer's device has been approved for cervical use and which devices have not, it cannot be deemed to be an exercise of professional "medical judgment" for a physician to unwittingly prescribe one of Defendants' devices for such a purpose. Defendants' reverent defense of a doctor's freedom to expand the horizons of medical science through "off-label" applications consequently rests upon a wholly unsupported premise.

[7] In fact, the success of Defendants' scheme would appear to be far better served by keeping the physician as much out of the process as possible, which they appear to have accomplished. (SAC (doc. 37-2), ¶¶ 34-51, pp.19-29.)

an "off-label" prescription, such knowledge on the part of the physician would not alter the Defendants' liability, because *it is the Defendants*, not the doctors, who then directly present the false claims for payment.

Given these circumstances, the purported "lack of particularity" in the SAC concerning a "promotion" scheme is truly beside the point. (Doc. 46, 18:8-20.) When the actual theory of liability is brought into focus (and the correct controlling authority is applied), the basis for Defendants' argument evaporates.

Defendants may have convinced themselves that the dismissal of the SAC is a foregone conclusion, but in several important respects, the foundation of their arguments rests on shaky ground indeed. Thus, to halt all progress in this case by imposing an absolute ban on all discovery proceedings would be both prejudicial and inefficient.

III. DEFENDANTS OVERRATE THE SUPPOSED BURDENS DISCOVERY WILL IMPOSE UPON THEM, AND UNDERRATE THE PREJUDICIAL DELAY WHICH WILL QUITE CERTAINLY RESULT FROM THE ABSOLUTE STAY OF DISCOVERY THEY SEEK.

In an apparent effort to deflect attention from the obvious delay which will result from their requested stay, Defendants point an accusatory finger at the Relators: "Given that the Relators have already delayed this matter by filing two

complaints since they filed the case in October 2012, a stay pending resolution of a potentially dispositive motion will not cause a prejudicial delay." (Doc. 51, 8:10-14.) Defendants overlook the fact that, by statute, a relator in any *qui tam* action cannot serve the complaint unless and until the Court orders the case to be unsealed and allows the complaint to be served upon the Defendants. 31 U.S.C. § 3730 (b)(2). In this case, the Court did not order the case to be unsealed until May 23, 2013 (doc. 10), and it was not until July 19, 2013 that the docket was unsealed. Relators served the First Amended Complaint on all Defendants by October 11, 2013, less than three months later.

On October 28, 2013 Relators counsel conducted a meet-and-confer with counsel for all Defendants and advised them of Relators intention to file the SAC. The parties thereafter entered into a stipulation[8] agreeing on a short deadline for Relators to file the SAC, accompanied by a Rule 15 motion, and extending the time for Defendants to file a responsive pleading until after the court ruled on the Rule 15 motion. On November 7, 2013, Relators served Defendants with the SAC and the following day filed the SAC (doc. 43) accompanied by the Rule 15 motion (doc. 33). After nearly six weeks of examining the SAC and the motion, on December 18, 2013, Defendants ultimately filed a Non-Opposition to Relators' Rule 15 Motion.

[8] Doc. 25, so Ordered 11/8/13 at Doc. 36.

Where Relators served the First Amended Complaint on October 11, 2013, less than three months after the Case was fully unsealed, informed Defendants of their intent to file a Second Amended Complaint on October 28, 2013, a mere two-and-a-half weeks later, and then served the Defendants with the SAC and the Rule 15 motion on November 7, 2013, just ten days after that -- and then had to wait six more weeks for the Defendants to decide that they did not oppose the Rule 15 motion after all, it hardly seems accurate to suggest that it has been the Relators who have thus far caused unnecessary delay. Nor is it accurate to suggest that no prejudice will result to Relators if the Defendants' request is granted.

In the normal course of the proceedings, many issues concerning discovery matters would have been addressed and resolved at this early stage, such as protective orders, identification of witnesses, locations of documents, and privilege logs. In light of the current procedural posture of the case, Relators were prepared to compromise and agree to tailor their discovery requests so that more burdensome discovery tasks might not have to be undertaken immediately. That possibility was foreclosed, not only by Defendants' sweeping Motion to Stay Discovery, but also by the position taken by the Defendants during the Rule 26(f) Conference conducted on February 13, 2014.

At that time, counsel for both defendants stated they would not agree to *any* discovery steps at this stage, not even Rule 26(a)(1) disclosures, due to their pending Motion to Dismiss and Motion to Stay Discovery. Thus, the stance Defendants have apparently adopted is that the stay they seek should be an across-the-board prohibition on *all* matters related to discovery, which would guarantee that absolutely nothing can be done to move this case forward until the Court issues its ruling on the Motion to Dismiss at some unknown future time.

Defendants' assert that "any" discovery the Relators would seek "would inevitably be broad in scope," as well as "costly and unwieldy." (Doc. 51, 4:16-18.) If , however, the normal course of case management and early meetings of counsel regarding discovery matters had not been interrupted by Defendants' current motion, the speculative burdens Defendants' envision could, by now, have already been well on their way to resolution between the parties *without* court intervention. Defendants' "parade of horribles" also overlooks the fact that much of the documentary discovery which the Relators will be seeking concern documents which these Defendants are already required by law to maintain and keep ready for inspection on short notice. Thus, the idea that *any* upcoming discovery will necessarily be "unwieldy," and require vast efforts coupled with burdensome expenditure, is simply not true.

Relators stand ready and willing to proceed expeditiously with this litigation, and to be forced to wait, not only the three months before oral argument on the Motion to Dismiss is scheduled to occur in May, but the unknown amount of time thereafter before the Court has the opportunity to consider and reach its decision, means that significant time, possibly even the better part of 2014, could be spent in limbo rather than in moving this case forward. To deny that such a potentially lengthy delay would be prejudicial to the Relators is to ignore the practical realities of litigation.

CONCLUSION

For the foregoing reasons, Relators submit that an absolute and immediate stay of all proceedings related to discovery would be both unwarranted and unwise. Relators therefore request that the Court deny Defendants' motion for stay, so that the usual proceedings undertaken pursuant to Federal Rules of Procedure 16 and 26 may go forward.

Dated: February 14, 2014

Respectfully submitted,

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